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TITLE: Automated Neuropsychological Assessment Metrics Version 4 (ANAM4): Examination of Select Psychometric Properties and Administration Procedures

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planning phase.

15. SUBJECT TERMS

ANAM, neurobehavioral, assessment, psychometrics, validity, reliability, normative

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collection for Study 1 is complete and nearing completion for Studies 2&3, with data analyses in progress. Study 4 is in the

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#### INTRODUCTION

The ability to accurately and efficiently monitor neurocognitive status of U.S. warfighters under diverse operational and experimental conditions is of critical importance to the ongoing mission and network-centered initiatives of the U.S. military. The Automated Neuropsychological Assessment Metrics Version 4 (ANAM4) is a computer-assisted tool for evaluating neurocognitive performance with demonstrated efficacy for application in diverse military operational and research testing scenarios. The primary objective of this multi-study project is to examine select psychometric and administration properties of the ANAM4. This project includes four studies that will 1) examine common use practices and determine the effect of specific administration procedures on ANAM4 performance (Study 1), 2) assess the test-retest reliability of individual ANAM4 tests (Study 2), 3) examine the validity of the ANAM4 mood scale (Study 3), and 4) develop a representative military normative dataset (Study 4).

### **Body**

This project was funded 01 December 2007. The approved study timeline/SOW is presented in **Table 1** (with task order revised Oct 2009).

TABLE 1: STATEMENT OF WORK: Study Timeline

Year	Year Months 1-2 Task 1 Plan and finalize		Plan and finalize logistics for Phase I (Studies 1-3)		
1	Months 3-12 (Dec 2008)	Task 2	Subject recruitment, data collection and data management for Studies 1-3		
	Month 13-14	Task 3	Perform preliminary data analyses for Study 3		
Year 2	Month 15-24 (Dec 2009)	Task 4	Complete data collection for Study 1		
		Task 5	Perform preliminary data analyses for Study 1		
		Task 6	Continue recruitment, data collection and data management for Study 2 & 3		
		Task 7	Complete data collection for Study 3		
Year 3	Month 25-36 (Dec 2010)	Task 8	Complete data collection for Study 2		
		Task 9	Plan and finalize logistics for Phase II (modified Study 4)		
		Task 10	Complete data analyses for Studies 1, 2, 3		
		Task 11	Preparation of journal manuscript(s) for Studies 1, 2, 3		
		Task 12	Preparation of Project report for Studies 1, 2, 3		
		Task 13	Initiate Phase II, Study 4		
Year 4	Month 37-48 (Dec 2011)	Task 14	Complete data collection for Study 4; Perform data analyses for Study 4		
		Task 15	Prepare Study 4 manuscript for peer review		
	Task 16		Preparation of Project Final Report		

Progress made during the funding period (01 December 2007 - 30 November 2008), corresponding to Tasks 1-4, was reported in the 2008 Annual Report. **Progress made during the 01 December 2008 - 30 November 2009 funding period, corresponding to Tasks 1-7, is reported below**.

Initial USARIEM Human Use Review Committee (HURC) approval for this project was received on 14 June 2007 (initial approval pending modification given on 23 May 2007). However, approval for Study 4 (normative data collection) was tabled on 11 January 2008 by the HURC due to the lack of a confirmed site(s) for data collection and potential duplicative efforts and other current research endeavors. It was decided that review of Study 4 by the HURC would be made at a later date.

#### **Task 1 (Month 1-2)**

## Plan and finalize logistics for Phase I - COMPLETED

All logistical aspects for HURC approved studies (Studies 1-3) have been confirmed. Recruitment procedures, equipment, testing facilities, and other data collection elements are operating and/or being carried out smoothly and as anticipated.

# <u>Task 2 (Month 3-12)</u> Subject recruitment logistics, data collection and data management for Studies 1-3 – COMPLETED

Subject recruitment, data collection and data management efforts are ongoing and on track. Recruitment of both Human Research Volunteers and Civilians has been effective and efficient.

### Task 3 (Month 15-24) Perform preliminary data analyses for Study 3– COMPLETED

Study 3 examines the validity of the ANAM4 mood scale. The original recruitment goal for Study 3 was 50 participants, which was achieved during the current performance period. Upon preliminary analyses, we noted differences between military and civilian participants on discrete mood parameters. However, the distribution of civilian to military participants in this sample was sufficiently disproportionate so as to prohibit any statistical comparisons between groups. Also, the military-civilian sample differed with respect to gender distribution (fewer females in the military sample) and education (fewer military males with greater than 18 years of education or more). In order to more fully explore these differences, a study amendment was submitted and approved to increase enrollment to a total of 80 participants, over-sampling for military women and military men with advanced degrees.

Within the current reporting period, a total of 68 participants have participated in Study 3. Additional recruitment is expected to be complete in the near future and data analyses and manuscript preparations are on target.

#### Task 4 (Month 15-24) Complete data collection for Study 1– COMPLETED

Study 1 involves the examination of common use practices and specific administration procedures (individual or group administration, practice or no practice, single session or two sessions) on ANAM4 task performances. Our recruitment goal for Study 1 is 99 participants, roughly 30 participants per condition (at least 15 per cell). This goal has been reached.

Table 2. Final number of Participants completing Study 1 conditions

		# of participants recruited
Condition 1	individual	41
Condition 1	group	15
Condition 2	practice	41
Condition 2	no practice	15
Condition 3	single session	41
Condition 3	double session	15

• Note that more than 30 participants consented to participating in more than one condition and/or more than one study, thus increasing sample numbers above expected recruitment goals in certain cells.

## Task 5 (Month 15-24) Perform preliminary data analyses for Study 1– COMPLETED

Preliminary analyses (sample characterization and demographic analyses) on the Study 1 data set have been completed and we are currently performing between group analyses and comparisons.

## <u>Task 6 (Months 15-24)</u> Subject recruitment, data collection and data management for Studies 2 & 3 – IN PROGRESS

As described above, we are in the final stages of participant recruitment for the amended Study 3. Study 2 involves the examination of practice effects and test-retest reliability. The following table (**Table 3**) shows recruitment progress for Study 2 within the reporting period. As with Study 1, our recruitment goal for Study 2 is 99 participants, roughly 30 participants per test-retest condition (days 1 & 7 / days 1 & 30 / 7 consecutive day retest). The goal for condition 1 & 3 has been reached.

TABLE 3. Participants completing Study 2 conditions (to date)

		# of participants recruited
Condition 1	1 and 7	30
Condition 2	1 and 30	18
Condition 3	7 consecutive	30

### Task 7 (Month 15-24) Complete data collection for Study 3– IN PROGRESS

As described above, the additional recruitment of 12 persons is expected to be complete in the near future and data analyses and manuscript preparations are on target.

**NOTE:** Study 4, as originally conceptualized for this grant, has already been conducted as part of ongoing efforts within the DoD to develop normative ANAM 4 data for use within a military-specific population. In an effort to avoid redundant efforts and address new and emerging gaps within the ANAM 4 literature, we are currently re-examining the specific aims of Study 4. We plan to propose a revised Study 4 research design to the funding sponsor for consideration in the near future (within 60 days). The modified Study 4 plan will be submitted to the USARIEM HURC and HRPO for all necessary reviews and approvals.

#### KEY RESEARCH ACCOMPLISHMENTS

Key research accomplishments during the current study period include:

- Data collection is complete for Study 1
- Data collection is on target for Studies 2 and 3. Data collection for Study 2 is nearly 90% complete. Following our supplemental amendment to Study 3 in 2009, Study 3 is 60% complete. We anticipate completion of Study 2& 3 data collection within the next 4 months.
- Data analysis and manuscript preparation for Study 1 is underway.
- Preliminary data analyses for Study 3 have been completed and manuscript preparation has been initiated.
- Continuing Review report was reviewed and approved by the USARIEM HURC (09 April 2009)

#### REPORTABLE OUTCOMES

#### 1. Reports, manuscripts, abstracts

Dr Proctor was invited to give a talk on prospective neuropsychological assessment at the Conference 'Issues and Challenges with Rapid Neuropsychological Assessment', convened by the University of Toronto Concussion Program, University of Toronto, Toronto Canada, 10-11 Dec 2009. (Abstract is included in the Appendix.)

Manuscript preparations are in progress for aspects of Study 1 and Study 3.

#### 2. Degrees and research training opportunities

One graduate level student, one master's level student, and two undergraduate students have been trained to administer the study protocol for this project.

#### 3. Collaborative funding applications related to work supported by this award

Dr. Heaton is site PI on a study examining the effects of fatigue on attention as measured by performance on an eye tracking task in a military population. This study, "Eye-Tracking Rapid Attention Computation (EYE-TRAC)" (USARIEM Protocol # H09-07) was funded as a CDMRP Advanced Technology Award in FY08. This project includes an ANAM4 task battery (ANAM 4 TBI Battery) as part of the protocol, with ANAM 4 data being collected at 4 time points, allowing for computation of test-retest reliability across a 2 week interval and sensitivity of the ANAM4 TBI battery to differentiate performance between a rested and fatigued (24 hour sleep deprivation) state.

#### 4. Related projects and collaborations initiated

Drs. Proctor and Heaton have initiated another study focused of the ANAM4. Specifically, the study is designed to examine the validity of the ANAM4TBI task battery in a case-control study design involving mild TBI/concussion patients, non-head injured patients, and healthy controls (USARIEM #H09-08).

#### **CONCLUSIONS**

There has been significant progress in this current funding period. Data collection for Study 1 is complete. We anticipate success in completion of final subject recruitment efforts for Study 2 & 3 and the initiation of Study 4.

Data from this project will add significantly to the development and use of ANAM4 and subsequent versions of the neurocognitive assessment tool, as well as provide useful information regarding use and of this assessment tool and interpretation of testing result within a military population.

## **APPENDIX**

ABSTRACT for invited talk at the conference 'Issues and Challenges with Rapid Neuropsychological Assessment', University of Toronto Concussion Program, University of Toronto, Toronto Canada, 10-11 Dec 2009

## Prospective Assessment of Neuropsychological Functioning Associated with Military Deployments

CORRESPONDING AUTHOR: Susan P. Proctor, D.Sc. U.S. Army Research Institute of Environmental Medicine, Kansas St. Bldg. 42, Natick, MA 01760, USA

In this presentation, two prospective epidemiological studies designed to examine neuropsychological performance changes related to deployment will be described. In each study, assessments were conducted prior to deployment and then within several months of return from deployment. Also, each study included a comparison group of soldiers not deployed over the study period. One study focused on a peacekeeping mission to Bosnia, while the other study involved a war-zone deployment mission to Iraq.

Although increasing medical attention is being focused on better understanding the physical and mental health consequences of deployment and the underlying risk and resilience factors, there are many knowledge gaps. Prospective evaluation of neuropsychological performance patterns following varying deployment scenarios, and thus occupational settings, can provide further insight for more targeted protection, prevention, and treatment strategies.

[The views expressed in this presentation are those of the author and do not reflect the official policy of the Dept of the Army or the Department of Defense.]

NOTE: Aspects of the research studies described in this presentation have been reported on previously at several conferences and in published articles (Vasterling et al., 2006; Proctor et al., 2009).

-Vasterling JJ, Proctor SP, Amoroso PJ, Kane R, White RF. Neuropsychological outcomes of Army personnel following deployment to the Iraq War. JAMA 2006; 296:519-529.

-Proctor SP, Heaton KJ, Dos Santos KD, Rosenman ES, Heeren T. Prospective assessment of neuropsychological functioning and mood in US Army National Guard personnel deployed as peacekeepers. Scandinavian Journal of Work, Environment and Health 2009; 35:349-360.